



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

21 December 2021  
EMA/498400/2021  
Press office

## Recommendations on eligibility to PRIME scheme

Adopted at the CHMP meeting of 13-16 December 2021

During its December 2021 meeting, the CHMP reviewed 4 recommendations for eligibility to PRIME: 1 were granted and 3 were denied. In addition, 1 request was withdrawn.

The individual outcomes adopted this month are listed below.

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## Eligibility granted

Name*	Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
ARI-0001	Advanced Therapy Medicinal Product	Oncology	Treatment of patients older than 25 years with relapsed/refractory acute lymphoblastic leukaemia	Nonclinical + Clinical exploratory	Academic sector

\* Name of the active substance, INN, common name, chemical name or company code.

SME applicants are micro-, small-and medium-sized-enterprises registered with the Agency's SME office. Other types of applicants are those not qualifying or not registered as SME or not fulfilling the definition of academic sponsors.

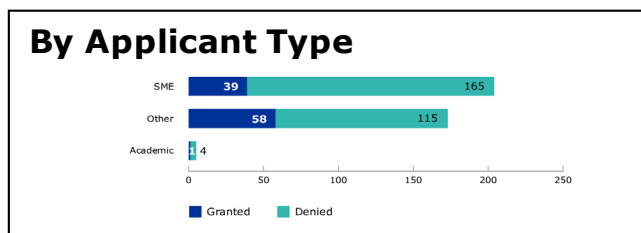
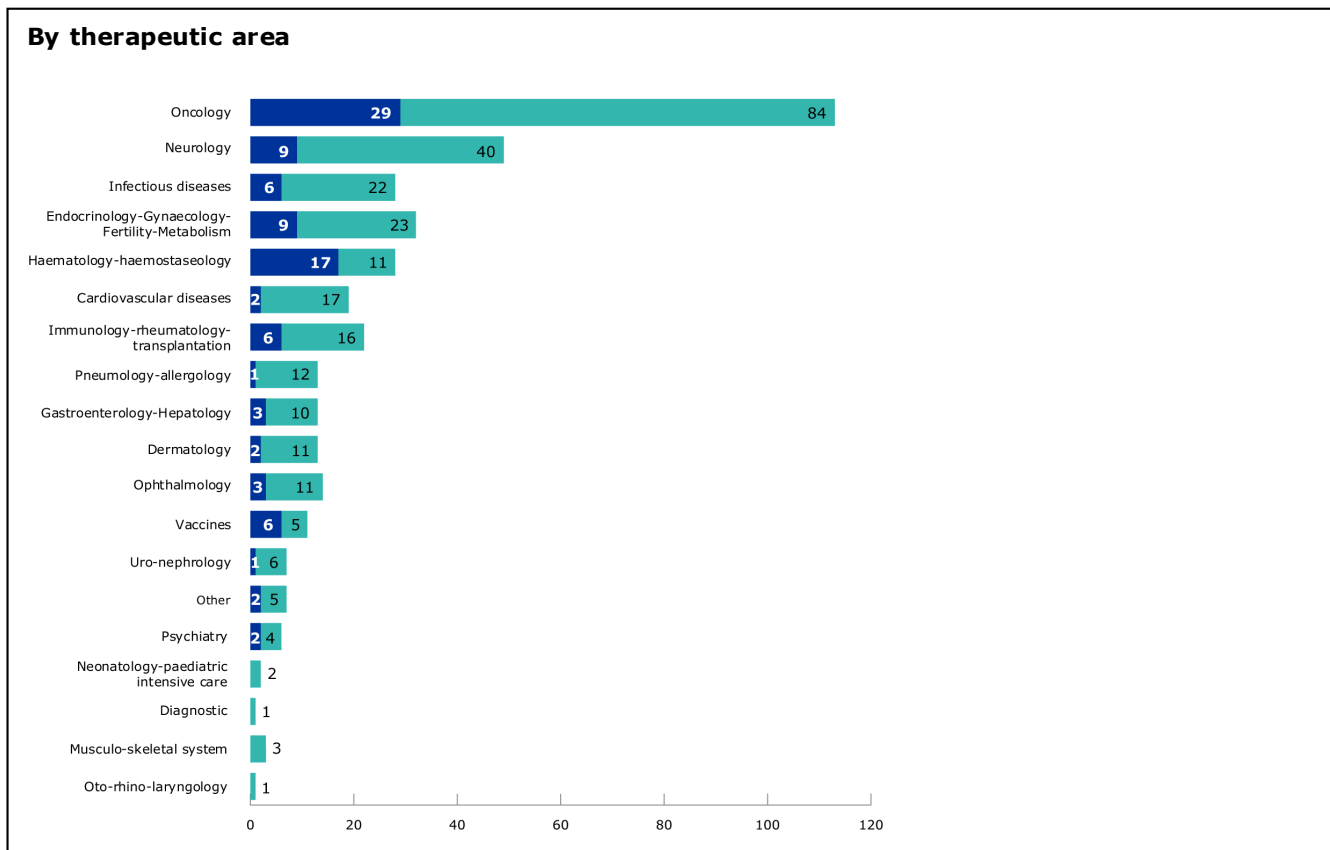
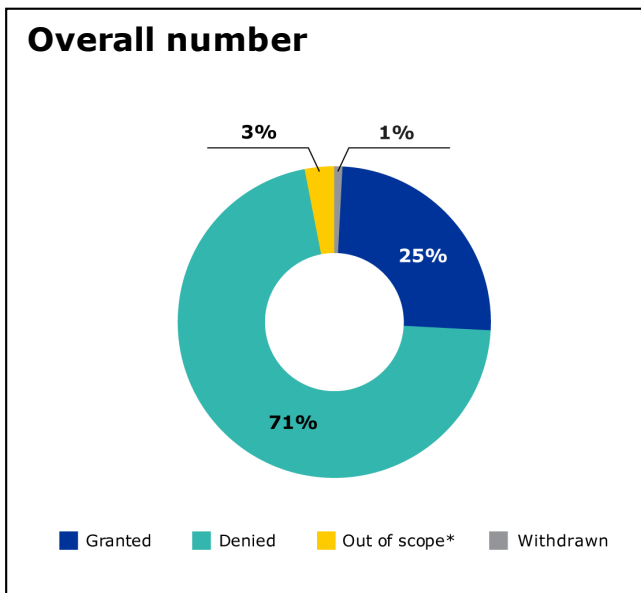
## Eligibility denied

Substance type	Therapeutic area	Therapeutic indication	Type of data supporting request	Type of applicant
Advanced Therapy Medicinal Product	Oncology	Treatment of advanced cutaneous melanoma	Nonclinical + Clinical exploratory	Other
Chemical Medicinal Product	Gastroenterology-Hepatology	Treatment of alpha-1 antitrypsin deficiency (AATD)-associated liver disease	Nonclinical + Clinical exploratory	Other
Biological Medicinal Product	Infectious Diseases	Prevention of recurrent Clostridioides difficile infection (rCDI) in patients at high risk of recurrence	Nonclinical + Clinical exploratory	Other

SME or not fulfilling the definition of academic sponsors.

# Cumulative overview of PRIME eligibility recommendations adopted by 16 December 2021

■ Granted ■ Denied ■ Out of scope\* ■ Withdrawn



\* This indicates eligibility requests received but not started by EMA as they were deemed outside the scope of the scheme or with a format and content inadequate to support their review. These are not included in the breakdown by type of applicant or by therapeutic area.